



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 24 2004

Witt Biomedical Corporation  
c/o Mr. Elfriede Pagan  
RA Specialist  
305 North Drive  
Melbourne, FL 32934

Re: K033030  
Trade Name: Calysto Series IV, Patient Care Monitors and Central Station, and ECG  
Management System  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac Monitor (including cardiometer and rate alarm)  
Regulatory Class: II (two)  
Product Code: 74 MWI  
Dated: December 18, 2003  
Received: December 22, 2003

Dear Mr. Pagan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

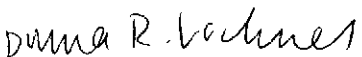

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Elfriede Pagan

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K033030

Device Name: CALYSTO Series IV, Patient Care Monitor and Central Station, and ECG Management System

### Indications For Use:

The CALYSTO Series IV is intended for complete physiologic/hemodynamic monitoring, clinical data acquisition and analytical assessment for cardiac catheterization, invasive radiology and electrophysiology laboratories. Its users, responsible to interpret the data made available, will be professional health care providers. CALYSTO Series IV provides the ability to transmit patient data files for storage, analysis and viewing at distributed locations within the clinical facility via intranet or internet, or may function as a stand-alone device.

Use of CALYSTO Series IV is not intended where unattended patient monitoring is desired or in situations where arrhythmia detection is required.

The CALYSTO Central Station and Patient Care Monitors are intended for complete physiologic monitoring, clinical data acquisition and analytical assessment within any healthcare environment. Its users, responsible to interpret the data made available, will be professional health care providers. User adjustable alarms (both visual and audible), alert the operator to anomalous occurrences and facilitate timely responses.

Use of CALYSTO Central Station and Patient Care Monitors is not intended where unattended patient monitoring is desired or in situations where arrhythmia detection is required.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Volchek  
(Division Sign-Off)  
Division of Cardiovascular Devices

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## Indications for Use

510(k) Number (if known): K033030

Device Name: CALYSTO Series IV, Patient Care Monitor and Central Station, and ECG Management System

### Indications For Use:

The CALYSTO Series IV ECG Management system is intended for receiving and storing resting, stress and holter ECG data from source devices. ECG data is stored, unaltered, in its original format, and made available for review and procedural report generation purposes. CALYSTO Series IV does not provide interpretive functions, but does store interpretive statements generated by the source device in an integrated and expandable database. Its users, responsible to interpret the data made available, will be professional health care providers. CALYSTO Series IV provides the ability to transmit ECG data files for storage, analysis and viewing at distributed locations within the clinical facility via intranet or internet, or may function as a stand-alone device.

Prescription Use ☒             
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Diana R. Vachon*  
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